AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 08/991143 Filing Date: December 16, 1997

Title: METHODS TO TREAT UNDESIRABLE IMMUNE RESPONSES

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In the Claims

Please amend the claims as follows:

- 1. (Currently Amended) A method of preventing or inhibiting a pathological condition associated with aberrant, pathogenic or undesirable antibody production which is specific for a particular endogenous antigen that is normally expressed in a human, comprising: administering to the respiratory tract of a human afflicted with, or at risk of, the pathological condition a dosage form comprising an amount of at least one epitope peptide, wherein the administration of the dosage form is effective to reduce or inhibit the aberrant, pathogenic or undesirable antibody production in humans having divergent HLA haplotypes, wherein the sequence of the epitope peptide comprises a universal, immunodominant epitope, and wherein the peptide comprises less than the sequence of the endogenous antigen, and wherein the endogenous antigen is an acetylcholine receptor; or factor VIII or factor IX.
- 2. (Canceled)
- 3. (Original) The method of claim 1 wherein the administration is effective to reduce or inhibit the amount of said antibody for an antigen comprising said peptide.
- 4. (Canceled)
- 5. (Currently Amended) The method of claim 1 wherein the endogenous antigen is factor VIII or factor IX.
- 6-16. (Canceled)
- 17. (Currently Amended) A method to tolerize a human to an endogenous antigen associated with aberrant, pathogenic or undesirable antibody production in the human, comprising: administering to the respiratory tract of the human at least one epitope peptide, having a

universal immunodominant epitope sequence, wherein the administration is effective to tolerize CD4⁺ cells which are associated with antibody production to the endogenous antigen; in humans having divergent HLA haplotypes, and wherein the peptide comprises less than the sequence of the antigen, and wherein the endogenous antigen is an acetylcholine receptor; or factor VIII-or factor IX.

- 18. (Original) The method of claim 17 wherein the peptide is nasally administered.
- 19-30. (Canceled)
- 31. (Previously Presented) The method of claim 1, or 17 wherein the administration does not increase synthesis of pathogenic antibody to the native antigen.
- 32-33. (Canceled)
- 34. (Previously Presented) The method of claim 1 wherein the administration is effective to reduce or inhibit the affinity of the antibody for an antigen comprising said peptide.
- 35. (Canceled)
- 36. (Currently Amended) The method of claim 34 wherein the endogenous antigen is factor VIII-or factor IX.
- 37-38. (Canceled)
- 39. (Previously Presented) The method of claim 1 or 17 further comprising administering an agent that inhibits B cell activation.
- 40. (Canceled)

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- 41. (Currently Amended) The method of claim 17 wherein the endogenous antigen is factor VIII-or factor IX.
- 42. (Currently Amended) A method of preventing or inhibiting a pathological condition associated with aberrant, pathogenic or undesirable antibody production which is specific for a particular endogenous antigen that is normally expressed in a human, comprising: administering to the respiratory tract of a human afflicted with, or at risk of, the pathological condition a dosage form comprising an amount of at least one epitope peptide, wherein the administration of the dosage form is effective to reduce or inhibit the aberrant, pathogenic or undesirable antibody production in humans having divergent HLA haplotypes, wherein the sequence of the epitope peptide comprises a universal, immunodominant epitope, and wherein the peptide comprises less than the sequence of the endogenous antigen, and wherein the peptide includes residues 150-169, 181-200 or 360-378 of the *Torpedo californica* acetylcholine receptor alpha subunit or a portion of those residues or corresponding residues in human acetylcholine receptor.

43. (Canceled)

44. (Currently Amended) A method of preventing or inhibiting a pathological condition associated with aberrant, pathogenic or undesirable antibody production which is specific for a particular endogenous antigen that is normally expressed in a human, comprising: administering to the respiratory tract of a human afflicted with, or at risk of, the pathological condition a dosage form comprising an amount of at least one epitope peptide, wherein the administration of the dosage form is effective to reduce or inhibit the aberrant, pathogenic or undesirable antibody production in humans having divergent HLA haplotypes, wherein the sequence of the epitope peptide comprises a universal, immunodominant epitope, and wherein the peptide comprises less than the sequence of the endogenous antigen, wherein the antigen is factor VIII.

- 45. (Previously Presented) The method of claim 42 wherein the administration is effective to reduce or inhibit the amount of said antibody for an antigen comprising said peptide.
- 46. (Previously Presented) The method of claim 42 wherein the administration does not increase synthesis of pathogenic antibody to the native antigen.
- 47. (Previously Presented) The method of claim 42 wherein the administration is effective to reduce or inhibit the affinity of the antibody for an antigen comprising said peptide.
- 48. (Currently Amended) The method of claim 1, 5, 17, 36, 41 or 44 wherein the epitope peptide includes sequences from A2, A3 or C2 of factor VIII.
- 49. (New) The method of claim 1, 17 and 44 wherein a pool of factor VIII peptides is administered.
- 50. (New) The method of claim 49 wherein the pool includes sequences from A2, A3 or C2 of factor VIII.